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ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. 09/751,493 12/28/2000 UM-04985 Mark A. Burns 3280 23535 7590 08/12/2003 MEDLEN & CARROLL, LLP **EXAMINER** 101 HOWARD STREET SISSON, BRADLEY L **SUITE 350** SAN FRANCISCO, CA 94105 ART UNIT PAPER NUMBER

> 1634 DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

				Application No.		Applicant(s)	
			09/751,493		BURNS ET AL.		
	Offic	Action Summary		Examiner		Art Unit	
	٠			Bradley L.	Sisson	1634	
The MAILING DATE of this communication app ars on the cover sheet with the correspondence address							
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM							
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status							
1)⊠ Responsive to communication(s) filed on <u>21 April 2003</u> .							
2a)⊠	•	on is FINAL.	2b) Thi		non-final.		
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims							
4)🖾	Claim(s) <u>1-20</u> is/are pending in the application.						
•	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.						
6)⊠	Claim(s) <u>1-20</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. ☐ Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notice	e of Draftsper	es Cited (PTO-892) son's Patent Drawing Review sure Statement(s) (PTO-1449)				ry (PTO-413) Paper No Patent Application (PTo	

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. In view of the amendment to claims 1, 8, and 13, the rejection of claims under 35 USC 112, first paragraph, has been withdrawn.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 5. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US Patent 5,922,591) in view of Wilding et al., (US Patent 5,587,128) and Yamaguchi et al. (US Patent 3,965,047).
- 6. Anderson et al., teach of a microfluidic device comprised of silicon that is comprised of transport channels therein. Column 20 discloses the use of insulating material such as silicon dioxide and that the channels may be coated with a substance that enhances hydrophobicity. It is suggested that this type of insulating material may be used in combination with "electrical leads" that have been placed in the channel. The aspect of an "electrical lead" is met by the deposition of a "metallic layer" on the surface of the channel. Dimensions of channels are disclosed at column 18.
- 7. While Anderson et al., disclose the inclusion of heating means, they do not disclose that the heating elements are arranged in an array format such that fluid transport is achieved.
- 8. Wilding et al., disclose mesoscale polynucleotide amplification devices that are comprised of minute channels formed, through various means, in a silicon base or substrate (column 5, last paragraph). Column 6, second paragraph, and columns 14-15, teach explicitly of optionally coating the surface of the reaction chamber and/or the channel walls (applicant's transport channels) with silicon dioxide.
- 9. Wilding et al., further disclose that the device, in at least one embodiment, comprises a series of heating means that are arranged along a common flow path. The intent of the heating elements in the disclosure is for the denaturation of nucleic acid, not for fluid transport.

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- 10. Yamaguchi et al., teach using an array of heating elements so to achieve "differential heating."
- 11. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the aspect of an array of heating elements in a micro-channel with micro-scale channels and reaction chambers, fluid receiving means and organic materials such as cells and nucleic acids, as such would have afforded the ordinary artisan with a device that is capable of not only performing a variety of chemical/biochemical reactions such as PCR, but would have permitted such reactions to be done so in a device that self contains all of the required elements and reactants. In view of the well-developed nature of the devices and the reactions, the ordinary artisan would have had a reasonable expectation of success.

Response to arguments

- 12. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).
- 13. Agreement is reached where at page 8 of the response received 21 April 2003, it is asserted "Yamaguchi *et al.* does not teach fluid movement through a microdroplet transport channel that [*sic*] generated by differential heating. Instead, Yamaguchi *et al.* teaches [*sic*] fluid pumping devices." Such agreement, however, does not negate the obviousness rejection as applicant is arguing limitations not present in the claims. None of the claims specify that the fluid is propelled as a result of differential heating. While the claims do not positively recite the presence of additional elements, such as pumping means, such is not excluded. Attention is

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drawn to the use of the term "comprises" in each and every independent claim. The use of said term has been interpreted as allowing for the inclusion of added elements or components, even in major amounts.

- 14. Agreement is reached in that Yamaguchi et al., does not disclose microfabrication techniques. Such non-disclosure is not considered to negative the instant rejection as Yamaguchi et al., was relied upon not for being additive to the disclosures of Anderson et al., and Wilding et al., but for disclosing a desired means of heating where the heating means are arranged in a series or array, and are used to heat liquids (column 4, last paragraph), the very material that is allowed to flow through the devices of Anderson et al., and Wilding et al.
- 15. While Yamaguchi et al., does not teach microscale devices, it is noted that the primary and secondary references do disclose such devices, as well as heating elements. One of ordinary skill in the art at the time the invention was made would have been motivated to have incorporated a series of heating elements located in a microchannel as disclosed by Wilding et al., yet are arranged as disclosed by Yamaguchi et al., as such would have allowed for greater control over the heating of the liquid passing through the channel or chamber.
- 16. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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- 18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.
- 19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.
- 20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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21. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Bradley L. Sisson Primary Examiner

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BLS

August 9, 2003